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Attorneys for Defendant
Advanced Medical Optics, Inc.
David J. Cooner (DC 3417)
Zane C. Riester (ZR 1041)

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PATRICIA MUNION and DAVID MUNION Plaintiffs, vs. ADVANCED MEDICAL OPTICS Defendant.	CIVIL ACTION NO. 07-CV-5377 JUDGE JOSEPH H. RODRIGUEZ

DEFENDANT ADVANCED MEDICAL OPTICS, INC.'S PARTIAL OPPOSITION TO PLAINTIFFS' MOTION TO COMPEL PRODUCTION OF PONDER DOCUMENTS FROM DEFENDANT AND TO COMPEL THE DEPOSITION OF JANET RICHARDSON, ESQ. AND CERTAIN AMO CORPORATE DESIGNEES

Defendant Advanced Medical Optics, Inc. ("AMO") submits this Brief in partial opposition to Plaintiffs' Motion to Compel Production of Ponder Documents From Defendant and to Compel the Deposition of AMO's in-house counsel, Janet Richardson, Esq., and certain AMO Corporate Designees in New Jersey. Additionally, this Brief will respond to the directives given to counsel during the Court's telephone conference of March 23, 2009.

In response to the Court's Order of March 11, 2009 and Plaintiffs' Motion to Compel, AMO has worked with Plaintiffs' counsel in an effort to address these issues without additional motion practice. AMO's efforts have been successful with regard to two of the main issues in

Plaintiffs' motion, which have now been resolved to the satisfaction of both parties. Specifically, AMO has not objected to produce the Ponder documents and will present Ms. Richardson for deposition on April 1, 2009, at McCarter & English's offices in Newark, New Jersey. AMO is not opposing Plaintiffs' motion on these two issues.[1]

AMO does, however, object to the scope, location, and timing of Plaintiffs' Fed. R. Civ. P. 30(b)(6) deposition(s) and presently raises these objections with the Court. Specifically, AMO objects to certain categories of questions it believes are either irrelevant to the scope of Plaintiffs' "root cause" questioning or protected from disclosure by the work product/attorney client privileges. Additionally, AMO objects to the timing of some of Plaintiffs' Fed. R. Civ. P. 30(b)(6) line of questions. Plaintiffs' motion in this limited regard should be denied.

INTRODUCTION

This medical device product liability case involves a contact lens solution. Plaintiffs claim that the product, AMO's COMPLETE MoisturePLUS® MultiPurpose Solution ("COMPLETE MoisturePLUS® MPS"), is defective, and that the defect caused injury to Plaintiff Patricia Munion. AMO voluntarily recalled the product on May 25, 2007, the same day that it received notification from the Centers for Disease Control and Prevention ("CDC") and US Food and Drug Administration ("FDA") that there may be an association between the product and Acanthamoeba Keratitis ("AK"), an eye injury. The recall and surrounding events spawned immediate litigation, and AMO, in response, launched an internal corporate investigation that was orchestrated and managed by AMO's counsel, Janet Richardson, Esq.

By way of this motion, Plaintiffs seek to take discovery with respect to the scope of this

[1] We would add that we have, in essence, never opposed production of the Ponder materials on the merits. We advised counsel that we were constrained by a Protective Order in Ponder. We advised Plaintiffs' counsel that she needed to obtain from this Court an Order compelling production, and that our opposition to any motion on that score would be limited to the fact that the materials were subject to a Protective Order in Florida. Further, we have been willing to make Ms. Richardson available, albeit not in New Jersey. We no longer object to producing her here.

investigation and the efforts undertaken by AMO in response to the withdrawal. Such materials are naturally privileged and protected from disclosure. Requiring AMO to respond further to Plaintiffs' 30(b)(6) requests would be unduly burdensome and otherwise harm AMO and its defense. Accordingly, AMO respectfully requests that Plaintiffs' Motion be denied in this regard.

ARGUMENT

A. Ponder Deposition Transcripts and Exhibits

As stated above, AMO has agreed not to challenge Plaintiffs' request for production of the transcripts and exhibits from the Ponder v. Advanced Medical Optics. Inc. et al, case formerly venued in the Circuit Court, 4th Judicial Circuit, Duval County, Florida. Although these documents are protected as confidential by a case-specific Protective Order, recent decisions in both the JCCP California litigation and the Texas federal litigation have ordered the production of these documents. Additionally, Plaintiffs' counsel in this case has also recently signed the JCCP protective order as part of her agreement to participate in the cross noticing of depositions in the JCCP. In light of these developments, AMO will produce all Ponder documents responsive to Plaintiffs' document demands following the entry of an Order by this Court.

B. Location of the Deposition of Ms. Richardson

Further to this Court's Order of March 11, 2009, AMO has agreed to produce Ms. Richardson at McCarter & English's offices in Newark, New Jersey, on April 1, 2009. While AMO reserves its right to raise additional objections as to the location of the future depositions of AMO corporate witnesses that may be necessary in this litigation, with respect to the "root cause" deposition of Ms. Richardson, AMO has agreed to produce the witness in New Jersey on

April 1, 2009.[2] (Ms. Richardson will be produced in response to the Notice for her deposition, not in a Fed. R. Civ. P. 30(b)(6) capacity.)

C. Location, Scope, & Timing of Fed. R. Civ. P. 30(b)(6) Deposition

In response to Plaintiffs' Fed. R. Civ. P. 30(b)(6) Notice of Deposition, AMO objects to the extent that the notice requests testimony that is either privileged or outside the scope of Plaintiffs' "root cause" investigation. With respect to the topics pertaining to the FDA and CDC's involvement with the recall, AMO does not object and will identify Ms. Sandy Selvaggi as a Fed. R. Civ. P. 30(b)(6) witness. Ms. Selvaggi is the designee most capable of responding to topics 2 and 3. She is scheduled to be deposed in the JCCP on March 31, 2009. Plaintiffs' counsel is able to participate in that deposition, as she has in other JCCP depositions.

Plaintiffs' Fed. R. Civ. P. 30(b)(6) request, attached hereto as Tab 1, lists 9 potential topics of questioning. These topics can be broken down into three general categories:

- Questions related to inherently privileged topics (Topics 4,5,6,7);
- Questions related to the re-launch of COMPLETE MoisturePLUS® MPS (Topics 1,8,9);
- Questions regarding the FDA/CDC's involvement in the recall of COMPLETE MoisturePLUS® MPS (Topics 2,3).

We will address each category in turn.

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[2] AMO is willing to produce Ms. Richardson in New Jersey despite the wealth of authority that there is a "presumption that a defendant should be examined at [her] residence or the principal place of business..." Turner v. Prudential Insurance Company of America, 119 F.R.D. 381, 383 (M.D.N.C. 1988). See also Work v. Bier, 107 F.R.D. 789 (D.D.C. 1985) ("Absent exceptional circumstances, the deposition of a defendant corporation by its agents and officers should ordinarily be taken at its principal place of business"). Indeed, in Work, that Magistrate Judge stated that he "fully agree[d] with counsel for the defendants to the effect that the universally accepted rule in federal litigation is that, in the absence of special circumstances (such as an impoverished plaintiff and a very affluent defendant), a party seeking discovery must go where the desired witnesses are normally located." Id. at 792 n.4. These cases, we submit, are in keeping with local federal practice. We do not quarrel with producing Ms. Richardson in New Jersey, but respectfully submit that in so doing AMO does not waive its rights with respect to the location of the deposition of any other out-of-state witness.

1. Questions Regarding Inherently Privileged Topics

AMO objects to these areas (Topics 4,5,6,7) since they implicate privileged documents, knowledge, and thoughts that are otherwise non-discoverable. These topics are a bold attempt to invade AMO's privilege rights and gain the fruits of AMO's counsel's investigation regarding any association between COMPLETE MoisturePLUS® MPS and AK.. The Declaration of Ms. Richardson specifically describes what prompted the root cause investigation, how it was initiated and directed, and makes clear that it was the product of counsel's work in the defense of this litigation. Plaintiffs can question Ms. Richardson as to the basis of this Declaration and how the root cause investigation was initiated and directed, but unless this Court rules that the "root cause" investigation is not protected, Plaintiffs cannot inquire as to the specifics of the "root cause" investigation's scope, structure, and activities, which pertain directly to the impressions and work product of AMO's counsel.

2. Questions regarding the re-launch of COMPLETE MoisturePLUS® MPS

These areas relate to topics that are outside the scope of the "root cause" investigation and Ms. Richardson's Declaration. The motion practice giving rise to Plaintiffs' notice for the deposition of Ms. Richardson and any necessary AMO corporate designees pertained entirely to AMO's "root cause" investigation. Plaintiffs do not have the authority to conduct fishing expeditions on topics unrelated to the root cause investigation. Furthermore, and perhaps more importantly, AMO never re-launched COMPLETE MoisturePLUS® MPS. Any testimony related to AMO's launch of other product lines post recall, pertains to a topic that falls outside the scope of Plaintiffs' "root cause" inquiry at this time and AMO therefore objects to the timing

of this line of questioning.[3]

3. Questions regarding the FDA/CDC's involvement in the recall of COMPLETE MoisturePLUS® MPS

This issue is largely moot, given the up-coming deposition of Ms. Selvaggi in the JCCP.[4] While AMO believes that this line of questioning falls outside the scope of Plaintiffs' "root cause" investigation and Ms. Richardson's Declaration, it nevertheless has plans to produce a witness who can provide testimony with respect to this issue next week in the JCCP. In that regard, AMO is intending to produce Ms. Sandy Selvaggi on March 31, 2009. Ms. Selvaggi is the person most knowledgeable with regard to FDA/CDC's involvement in the recall of COMPLETE MoisturePLUS® MPS. As AMO previously stated, Plaintiffs have signed the JCCP Protective Order and have been participating in depositions cross noticed in this litigation. Plaintiffs will have a full opportunity to depose Ms. Selvaggi regarding the FDA/CDC's involvement in the recall of COMPLETE MoisturePLUS® MPS at this time.

# # #

In closing, therefore, as to these areas, some are going to be covered by Ms. Selvaggi on March 31 in the JCCP - specifically, topics 2,3. Topics 4, 5, 6 and 7 are objectionable as they invade the attorney client or work product privileges. And Topics 1, 8 and 9 pertain to issues beyond the scope of the current root-cause dispute. Furthermore, these topics address the re-launch of COMPLETE MoisturePLUS® MPS, a product that was never re-launched.

[3] While Ms. Richardson will not be offered as a 30(b)(6) witness, she would be able to confirm at her April 1 deposition that COMPLETE MoisturePLUS® MPS was never re-launched.

[4] Ms. Selvaggi will testify about "the recall of COMPLETE MoisturePLUS® MPS on or about May 25, 2007, including the decision to recall, the development of recall strategies, the implementation of the recall, changes in the regulatory status of the recall, and the effectiveness of the recall," among other issues, at her JCCP deposition.

CONCLUSION

For the foregoing reasons, AMO respectfully requests that Plaintiffs' Motion be denied in part.

McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102

/s/David J. Cooner
David J. Cooner

Attorneys for Defendant
Advanced Medical Optics, Inc.

Dated: March 23, 2009

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PATRICIA MUNION and DAVID MUNION Plaintiffs,	:	CIVIL ACTION NO. 07-5377 JUDGE JOSEPH H. RODRIGUEZ
vs.	:	
ADVANCED MEDICAL OPTICS	:	JURY DEMANDED

NOTICE OF DEPOSITION OF THE CORPORATE DESIGNEE OF ADVANCED MEDICAL OPTICS PURSUANT TO FEDERAL RULE 30(b)(6)

To: David J. Cooner, Esq.
Zane Riester, Esq.
McCarter & ENGLISH
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102

Counsel for Advanced Medical Optics

PLEASE TAKE NOTICE that pursuant to Rule 30(b)(6) of the Federal Rules of Civil Procedure, Plaintiffs Patricia and David Munion will take the oral deposition of the corporate designee of Advanced Medical Optics ("AMO") regarding any and all information concerning the following matters:

1. Preparation for re-introduction and/or re-launch of Complete Moisture Plus into the market after the May 2007 recall of the product, including marketing and public relations strategies.

2. Involvement with the FDA following the May 2007 product recall, including but not limited to all information, reports, data or other documents released or produced to the FDA.

3. Involvement with the CDC following the May 2007 product recall, including but not limited to all information, reports, data or other documents released or produced to the FDA.

4. Studies performed regarding Complete Moisture Plus after the May 2007 product recall.

5. Information collected regarding any alleged association between Complete Moisture Plus and Acanthamoeba Keratitis.

6. The identity, roles and activities of Defendant AMO employees and other persons involved in the "root-cause investigation."

7. Tests, activities, laboratory work and scientific methods developed and performed as part of the "root-cause investigation."

8. The identity and roles of Defendant AMO employees and other persons involved in development and performance of new product for re-launch into the market.

9. Studies, tests and activities performed regarding the development of new product for re-launch into the market, including but not limited to development of products to market in place of Complete Moisture Plus.

Defendant AMO shall designate one or more officer(s), director(s), managing agent(s), or other person knowledgeable about each of the above matters and may set forth for each person(s) they designate, the matters on which the person(s) will testify. The deposition will take place at Meyerson & O'Neill, 1700 Market Street, Suite 3025, Philadelphia, PA on March 6, 2009, beginning at 10:00 am.

The deposition will be taken before a person duly authorized to administer oaths

and shall continue from day to day until completed. You are invited to attend and participate.

Dated: February 13, 2009

Debora A. O'Neill
Emily L. Mirsky
MEYERSON & O'NEILL
1700 Market Street - Suite 3025
Philadelphia, PA 19103
(215) 972-1376
Attorneys for Plaintiffs

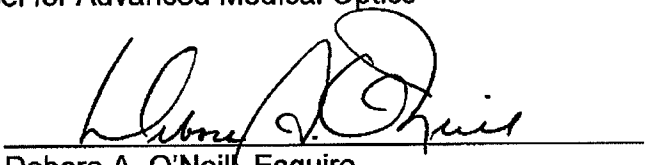
cc: Frank Frontino Court Reporting

CERTIFICATE OF SERVICE

I hereby certify that service of a true and correct copy of the foregoing Notice of Deposition was made on February 13, 2009 upon the parties listed by electronic mail and United States mail, first class, postage prepaid:

David J. Cooner, Esq.
Zane Riester, Esq.
McCarter & ENGLISH
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102

Counsel for Advanced Medical Optics



Debora A. O'Neill, Esquire

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

PATRICIA MUNION and DAVID MUNION Plaintiffs,	:	CIVIL ACTION NO. 07-5377 JUDGE JOSEPH H. RODRIGUEZ
vs.	:	
ADVANCED MEDICAL OPTICS	:	JURY DEMANDED

NOTICE OF DEPOSITION

To: David J. Cooner, Esq.
Zane Riester, Esq.
McCarter & ENGLISH
Four Gateway Center
100 Mulberry Street
Newark, NJ 07102

Counsel for Advanced Medical Optics

PLEASE TAKE NOTICE that pursuant to the Federal Rules of Civil Procedure, Plaintiffs will take the oral deposition of Janet M. Richardson, Esquire, of Advanced Medical Optics concerning any and all matters concerning or referenced in the Declaration of Janet Richardson in Support of Privilege Log, a copy of which is attached hereto as Exhibit "A". The deposition will take place at the offices of Meyerson & O'Neill, 1700 Market Street, Suite 3025, Philadelphia, PA on March 6, 2009 beginning at 2:00 pm. The deposition will be taken before a person duly authorized to administer

oaths and shall continue from day to day until completed. You are invited to attend and participate.

Dated: February 13, 2009

Debora A. O'Neill
Emily L. Mirsky
MEYERSON & O'NEILL
1700 Market Street - Suite 3025
Philadelphia, PA 19103
(215) 972-1376
Attorneys for Plaintiffs

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Attorney for Defendants
ADVANCED MEDICAL OPTICS, INC.
and ALLERGAN, INC.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF ORANGE

COORDINATION PROCEEDING SPECIAL TITLE (CRC 3.550(b)) **IN RE COMPLETE® CASES**	**Case No. JCCP 4521** Assigned to Honorable David C. Velasquez, Dept. CX-101, (714) 568-4802 **DECLARATION OF JANET M. RICHARDSON IN SUPPORT OF PRIVILEGE LOG**
Lead Case: MICHAEL CONNOLLY, et al. v. ADVANCED MEDICAL OPTICS, INC., et al.	OCSC Case No. 07CC01296
RELATED TO ALL ACTIONS.	

I, Janet M. Richardson, declare and state as follows:

1. I am an attorney at law, licensed to practice before all the Courts of the State of California, and I am Senior Managing Attorney for Advanced Medical Optics, Inc. ("AMO"), a

Exhibit "A"

position which I have held since January 2007. I have been employed by AMO as an attorney since February 2006.

2. This Declaration is based upon my personal knowledge and is made in support of AMO's privilege log, submitted in *In Re Complete® Cases*, JCCP 4521. This Declaration is an effort to provide the Court with background and contextual information concerning the documents identified in AMO's privilege log to allow the Court to assess AMO's assertion of attorney-client and attorney work product privileges. Although the information provided below describes what actions I took generally and what events prompted those actions, I have attempted to omit my thought processes and specifics regarding my/AMO's litigation strategies in order to avoid waiving the attorney-client and attorney work product privileges. By providing this information, I intend no waiver of any privilege.

3. On Friday, May 25, 2007, AMO was notified, during conference calls with the US Centers for Disease Control and Prevention (CDC) and the US Food and Drug Administration (FDA), that CDC had received information regarding a possible association between COMPLETE MoisturePLUS® Multi-purpose Solution and an infection known as acanthamoeba keratitis. Based upon that information, AMO immediately conducted a voluntary global recall of COMPLETE MoisturePLUS® MPS.

4. On Saturday, May 26, 2007, I had a lengthy conversation with Diane Biagianti, then AMO's Deputy General Counsel (now General Counsel), regarding the recall. Ms. Biagianti had attended the May 25 conference calls and was involved in discussions regarding the decision to recall, the execution of the recall, and communications announcing the recall. We discussed, among other things, the likelihood of products liability or other litigation by patients or shareholders. Because of my 15-year background in drug and device liability defense, and because CDC had interviewed patients who had experienced acanthamoeba keratitis and had used COMPLETE MoisturePLUS® MPS, there was no doubt in my mind that AMO would be named in products liability litigation. Ms. Biagianti and I discussed, among other things, the nature of the expected claims, the essential elements of products liability claims generally and how those elements might apply to the COMPLETE MoisturePLUS® MPS situation, legal defenses available to manufacturers of medical devices, and the types of information I would be interested to have in order to evaluate AMO's possible defenses and

prepare for litigation. As a result of that discussion with Ms. Biagianti, it became my task to gather data and information to defend such expected litigation and I started immediately.

5. On Tuesday, May 29, 2007, the first business day after the recall (Monday was Memorial Day), I saw a website entitled amokeratitislawyer.com, which stated that the "AMO Complete MoisturePlus Legal Group" was offering free case evaluations for people who had experienced any eye injury after using the product. A true and correct copy of this website page is attached hereto as Exhibit "A". Seeing this website further reinforced my early belief that AMO would be named in products liability litigation and that there was an urgent need to immediately begin gathering data and information to defend the company from expected litigation involving the product.

6. On Thursday, May 31, 2007, I learned that a lawsuit, *Nevada Truchan, et al. v. AMO*, had been filed in Canada on May 30. That matter was a purported class action brought by purchasers of COMPLETE MoisturePLUS® MPS.

7. On June 4, 2007, the fifth business day after the recall, the Moore Labriola firm filed the lawsuit *Connolly v. Advanced Medical Optics* in Orange County Superior Court. I was informed of this filing on June 4, 2007. I was well-acquainted with Mr. Moore from his days defending drug and device manufacturers in products liability litigation. I reviewed the complaint on June 6, 2007. A true and correct copy of the *Connolly* complaint is attached hereto as Exhibit "B".

8. My investigation commenced with requesting information regarding the allegation that an association existed between COMPLETE MoisturePLUS® MPS and acanthamoeba keratitis. The most significant aspect of the investigation I requested consisted of contacting and involving AMO's Research & Development Department to gather certain data and information regarding the purported association between the product and acanthamoeba keratitis. This was what we referred to as the root cause investigation. The communications pertaining to the root cause investigation, the implementation of which is further described below, make up the majority of the documents identified in the privilege log. However, as will also be explained further below, not all communications generated within AMO after the root cause investigation commenced have been withheld/are claimed to be privileged.

9. To implement my request for a root cause investigation, I had several conversations

with members of AMO's Eye Care R&D Department within the first week after receiving notice of CDC's investigation. Initially, we principally discussed possible defenses to the actual and expected litigation and my need for data regarding the recalled product, acanthamoeba keratitis, and any potential link between the two. Thus, over the next several days beginning in early June 2007, I had meetings with John Lally, Ph.D., AMO's Vice President of Eye Care R&D, to discuss AMO's defense and obtain his scientific input on hypotheses regarding the alleged association between the product and acanthamoeba keratitis as well as scientific methods that could be employed to test those hypotheses. I also attempted to personally gather whatever information other scientists had regarding acanthamoeba keratitis, so that such information could be evaluated.

10. Based on those discussions with Dr. Lally and my own research, I developed a list of tests and other investigational activities, and I instructed Dr. Lally to have those tests performed and investigations carried out, and to report the results to me personally so that I could use them in defense of litigation. To the extent that those tests could be performed in-house using AMO personnel, I asked that he do so, and that outside laboratories or researchers be engaged to address matters our personnel could not undertake. At my direction, this analysis and investigation was to be separate from any activities associated with development of a multi-purpose solution to market in place of COMPLETE MoisturePLUS® MPS. Also, during the course of these meetings with Dr. Lally to implement my request for a root cause investigation, I advised him that all personnel working on the investigation were to be informed that their work, and information learned, was to be strictly confidential, and that all results of tests and research and investigation was to be reported only to me/AMO's legal department.

11. Dr. Lally's in-house research and development team included, among others, Jim Cook, Kate Ambrus, Nancy Brady, Nooshin Azizi, Stan Huth, Hayes Powell. I also sought input and analysis from others within AMO, including Nicholas Tarantino, O.D. (AMO's Vice President of Clinical Affairs), Lynn Lasswell, O.D. (Director, Eye Care Clinical Research), and Leonard Bormann, Pharm. D. (Executive Vice President, Research & Development). Simon Kilvington, who is now an AMO employee but was at the time a member of the faculty of the University of Leicester in the United Kingdom, was engaged to assist in the testing and investigation, and I met and spoke with

Dr. Kilvington on multiple occasions during 2007 to discuss his findings. I also engaged Claude Anger as a litigation consultant; Mr. Anger has experience in acanthamoeba infections and efficacy testing, and was a longtime employee of Allergan who had performed and directed testing on Allergan multipurpose solutions. I also engaged Oliver Schein, an epidemiologist from Johns Hopkins.

12. The activities I requested of the investigative team included searches of literature for any prior studies by third parties that might provide useful information REDACTED ATTORNEY-CLIENT WORK-PRODUCT PRIVILEGE efforts to gather information REDACTED ATTORNEY-CLIENT WORK-PRODUCT PRIVILEGE from CDC and from physicians and scientists who had published articles REDACTED ATTORNEY-CLIENT WORK-PRODUCT PRIVILEGE engaging physicians and scientists as litigation consultants to provide input and guidance on REDACTED ATTORNEY-CLIENT WORK-PRODUCT PRIVILEGE epidemiology, AK pathology, and alternate causation and, in some instances, to perform laboratory work.

13. I met regularly with Dr. Lally and/or members of his team throughout the course of the investigation to discuss the progress of the research and its impact on our hypotheses and AMO's defense strategies. The primary research activities concluded in about November 2007, though I have continued to draw upon Dr. Lally and his team for advice and guidance on causation issues (both general and specific causation) throughout the litigation. Based on those discussions, and on my evaluation of publicly-available information as well as claims being made in various recall-related litigation matters, I provided revised or modified research instructions to the R&D group. All reports of testing performed by R&D were provided to me for my review and approval to ensure that the reports met my litigation needs.

14. Ultimately, from the moment AMO received the first word from the FDA and CDC that there was a potential link between COMPLETE MoisturePLUS® MPS and AK, we among the legal staff at AMO knew litigation was virtually inevitable and the tasks outlined above were conducted with that anticipation. It took only days for our suspicions to be borne out as suits were filed and claims were presented in both the US and Canada in the days following the recall.

15. After significant root cause work had been done for defense of litigation, I became aware that FDA was requiring information about AMO's investigative activities. A brief summary of

certain of AMO's key root cause findings were presented to FDA in November 2007. FDA regulations allow companies to indicate that certain information is exempt from disclosure under FOIA. FDA was notified that the information was considered to be privileged under attorney-client and attorney work product privileges as well as being proprietary, and that it should therefore not be disclosed.

16. AMO has been associated with three publications since the root cause investigation was commenced. One is a roundtable-type article entitled "What You Need to Know", and the other two are articles, one by Kilvington/Lally and one by Anger/Lally. At the conclusion of the key root cause work, AMO determined that the interests of science and public safety warranted public release of certain limited findings. Because they have been released publicly, AMO is not asserting that they are privileged. Nor did we intend, by releasing this information, to waive privileges with regard to the root cause investigation. None of these publications disclose the results of the root cause investigation or describe the root cause investigation. These publications were released because AMO felt that it was important that the FDA and the scientific community have knowledge of certain, limited scientific findings that emanated from the root cause investigation.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this declaration was executed at Santa Ana, California on October 13, 2008.

Janet M. Richardson